Risk Assessment & Risk Management of PFASs at U.S. EPA

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The views expressed in this presentation are those of the authors and may not reflect USEPA policy or endorsement

PFAS Risk Assessment & Management at US EPA

- Legacy Contamination
  - Office of Water
  - Office of Solid Waste and Emergency Response
  - Regional Offices

- Existing & New Chemicals
  - Office of Chemical Safety and Pollution Prevention
    - Office of Pesticide Programs
    - Office of Pollution Prevention & Toxics

- Emerging Issues & Approaches
  - Office of Research and Development

Office of Water: Safe Drinking Water Act

- Contaminant Candidate List (CCL)
  - Lists unregulated contaminants which may require a national drinking water regulation in the future
  - 2009: 3rd Contaminant Candidate List (CCL3) – listed PFOA & PFOS
  - 2014: DRAFT 4th Contaminant Candidate List (CCL4) – listed PFOA & PFOS

- Unregulated Contaminant Monitoring Regulation (UCMR3)
  - A requirement to monitor unregulated contaminants
  - Identify no more than 30 contaminants to be monitored every 5 years
  - 2011 UCMR: includes six perfluorinated chemicals
  - PFOA & PFOS Monitoring Status January 2015
    - PFOA 72 systems with detects; no systems > provisional value
    - PFOS 68 systems with detects; 12 systems > provisional value

PFOA and PFOS: Drinking Water Health Advisories

- Informal technical guidance to assist Federal, State and local authorities in responding to urgent or developing drinking water contamination

- 2009: Issued ***Provisional Health Advisories***
  - PFOA = 0.0004 mg/L
  - PFOS = 0.0002 mg/L

- 2014: Draft ***Health Effects Documents***
  - Support development of Lifetime Health Advisory Values to replace the provisional values
  - Provide Reference Dose and Cancer Classification for each chemical
  - Peer reviewed September 2014; Anticipate completion end of 2015
  - May serve as index chemicals for Relative Potency Factors applicable to other PFASs

Office of Solid Waste & Emergency Response

- 2008: DoD Knowledge Based Corporate Reporting System
  - 594 DoD facilities have been categorized as Fire/Crash/Training Sites and, therefore, have the potential for PFC contamination based on historical use of Aqueous Film Forming Foam (AFFF)

- 2013: Superfund Information Systems Database:
  - PFCs have been reported in the 5-year reviews of 14 hazardous waste sites on the EPA National Priorities List

- 2014: Emerging Contaminants Fact Sheet – PFOS and PFOA
  - http://www2.epa.gov/sites/production/files/2014-04/documents/factsheet_contaminant_pfos_pfoa_march2014.pdf

- EPA Regional Offices & States
  - Addressing site-specific contamination issues

Office of Research and Development

- PFC research underway at multiple EPA labs
- ORD research supports understanding of PFC sources and exposure pathways
- Conducting research in several areas, including:
  - Telomer biodegradation research
  - Methods development for environmental, biota, and biological matrices
  - Aged article research
  - Distribution in environmental matrices
  - Toxicology and pharmacokinetics

Office of Chemical Safety & Pollution Prevention

Pesticides & Industrial Chemicals

Office of Pesticide Programs: Sulfuramid Phaseout

- Termiticide; major degradate is PFOS
- 2001: Negotiated phase-out of all registrations to end 2016; sole registrant agrees to discontinue production
- 2007: Reregistration Review; technical registrant supply exhausted
- 2008: Product Cancellation Order ends manufacturing-use registrations
- Phase-out renegotiated to end all product registrations by 2012;
  - End-use registrants permitted to sell remaining stocks for 1-year
  - Distributors and retailers permitted to sell existing stocks of 7 registered end-use products

Federal Register / Vol. 73, No. 96 / Friday, May 16, 2008

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2007–1082; FRL–8364–2]

Sulfluramid; Product Cancellation Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellation, voluntarily requested by the registrant and accepted by the Agency, of products containing the pesticide sulfluramid, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This cancellation order follows a December 19, 2007 **Federal Register** Notice of Receipt of Request from the sulfluramid registrant to voluntarily cancel the last remaning sulfluramid manufacturing-use product (MUP) registration. In the December 19,

Office of Pesticide Programs: Inert Ingredient Tolerance Revocation

- 2006: revoked safe tolerance levels for as many as 130 inert pesticide ingredients currently exempted from tolerance levels
  - including PFOA related chemicals
  - because there was insufficient data available to make a safety determination.

Risk Assessment & Risk Management under the Toxic Substances Control Act (TSCA)

TSCA Assessment Paradigms

- EPA evaluates and regulates, as appropriate, the full life cycle, i.e., manufacture (import), distribution, use, and disposal, of industrial chemicals
  - Safety Evaluation for a wide diversity of Industrial Chemicals: Existing and New Industrial Chemicals Pre-Manufacture Notification (PMN)
  - Data Availability/Quality Varies, but generally limited/incomplete

- Existing Chemicals
  - Established Test Guidelines; most testing for toxicity is *in vivo*
  - Read-Across from Analogs/Categories used extensively in screening programs

- New Chemicals
  - Computational approaches used extensively (e.g., QSAR, Expert Systems, Read-Across from Analogs, Chemical Categories
  - Tiered-Testing Approach: requests for higher tiered testing contingent on screening results

Office of Pollution Prevention & Toxics
2010/2015 PFOA Stewardship Program

- 2006: Eight major fluoropolymer and telomer manufacturers invited to join in a global stewardship program with two goals
  - No later than 2010, a 95 percent reduction in:
    - facility emissions to all media of PFOA, precursor chemicals that can break down to PFOA, and related higher homologue chemicals, and product content levels of these chemicals.
  - Work toward elimination of these chemicals from emissions and products by 2015.

- Participating companies:
  - Submitted baseline year 2000 data on emissions and product content (2006)
  - Report annual progress toward goals each succeeding year and report progress in terms of both U.S. and global operations.

- 2015: EPA released companies' progress reports for 2013 and 2104
  - Results show that the companies are on track to reach the program's goal of phasing out these chemicals by the end of 2015.

Office of Pollution Prevention & Toxics
Regulatory Action on PFAS/LCPFAC Compounds

- **SNURs (Significant New Use Rules) – Only apply to uses NOT on-going**

- 2002 SNUR: **C8 Sulfonates**
  - 75 PFAS chemicals included in the voluntary phase out of PFOS by 3M that took place between 2000 and 2002.
  - Allowed the continuation of a few specifically limited, highly technical uses of these chemicals for which no alternatives were available and had very low volume, low exposure, and low releases

- 2002 SNUR: **Sulfonates of PFOA and higher/lower homologs**
  - 13 PFAS chemicals included in the voluntary phase out of PFOS by 3M that took place between 2000 and 2002
  - Allowed the continuation of a few specifically limited, highly technical uses of these chemicals for which no alternatives were available and had very low volume, low exposure, and low releases

- 2007 SNUR: **Sulfonates**
  - 83 PFAS chemicals believed to no longer be manufactured (including imported) or used in the United States.

- 2013 SNUR: **Carboxylates/Carpet**
  - Any new use of LCPFAC chemical substances as part of carpets or carpet treatment products
  - Also amended the PFAS SNUR to add PFAS chemical substances that have completed the TSCA new chemical review process, but have not yet commenced production or import, and to designate (for all listed PFAS chemical substances) processing as a significant new use

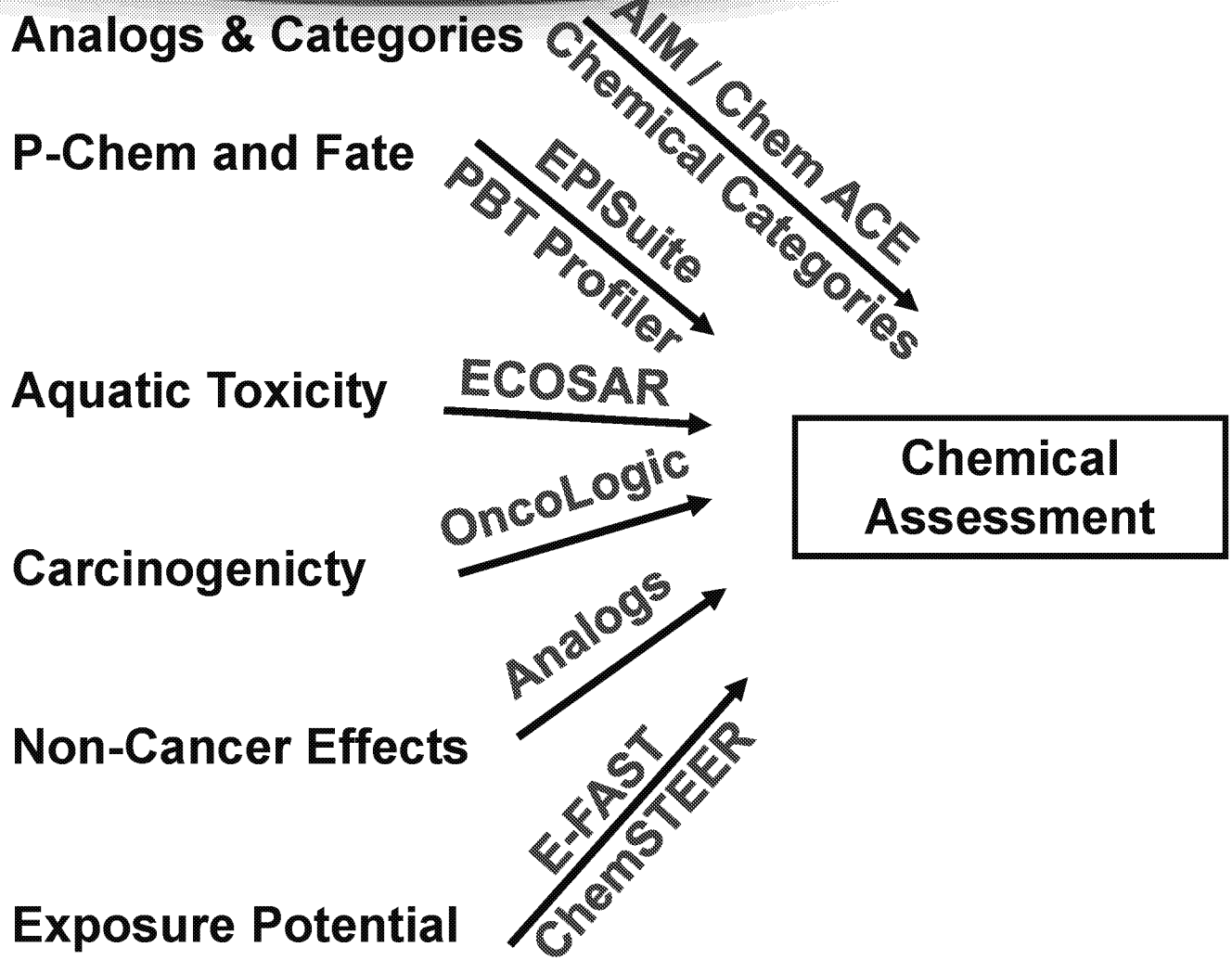
Regulatory Action on PFAS/LCPFAC Compounds: Proposed Rule

- January 2015: SNUR for Perfluoro Alkyl **Sulfonates** and Long-Chain Perfluoro Alkyl **Carboxylates** to ensure that phased-out chemicals do not re-enter the marketplace without EPA review.
- Specifically, the rule proposed to:
  - **Amend a SNUR** for long-chain perfluoroalkyl **carboxylate** chemical substances by designating as a significant new use manufacturing (including importing) or processing of certain LCPFACs for any use not ongoing after December 31, 2015, and all other LCPFAC chemicals substances for which there are currently no ongoing uses.
  - **Make inapplicable** the exemption for persons who import LCPFAC chemical substances as part of articles.
  - **Amend a SNUR for PFASs to** make inapplicable the exemption for persons who import PFAS chemical substances as part of carpets.

PFAS New Chemicals Pre-Manufacture Notices

- About 40-50 PMNs and LVEs
- 800+ since 1995
- Range from small, simple molecules to oligomers, to very large complex polymers.
- Diversity of structures: chain length from 2 or 3 up to >40 carbons; linear, branched, cyclic or other structures; other atoms such as O in the carbon chain.
- May be grouped into general categories or classes based on composition, chain length, molecular weight or other characteristics

Computational Tools: Critical to OPPT Assessments



TSCA New Chemical Review - Outcomes

Does EPA find that the chemical "may present unreasonable risk" to human health or the environment:

- NO: chemical allowed into commerce with no restrictions

- YES: several regulatory tools available to limit release and exposure:
  - Ban Pending Upfront Testing: in rare cases chemicals are banned pending testing
  - TSCA 5(e) Consent Orders:

- Consent Order typically contains some or all of the following requirements as conditions:
  - Testing for toxicity or environmental fate
  - Restrictions on distribution and use
  - Personal protective equipment for workers
  - Hazard communication language
  - Restrictions on releases to water, air or land
  - New Chemical Exposure Limits (NCELs) for worker protection
  - Recordkeeeping

New Chemical Assessment: Challenges

- Measured fate and toxicity data not required; generally not submitted
- Existing CBI and public data used whenever possible
- Estimation tools of limited use
- Data for possible analogs very limited so read across limited
- "EPA New Chemical Categories" and the efficiencies (e.g., structural, fate and effect similarities, testing schemes) they build into our program do not exist
- Requires large amount of "Professional Judgement"

PFASs Assessment "Rules of Thumb"

FATE

- Oxidized perfluoro end products are generally persistent; everything else will eventually form these.
- Saturated and some unsaturated perfluoro carboxylic acid and sulfonate end products are stable under most environmental conditions.
- Stable PFCs can have multiple precursor molecules; some may have hundreds.
- PFCs that are not highly oxidized may degrade to form multiple end products.
- PFC structures attached to hydrocarbon or other polymers by ester linkages are expected to release monomers that further degrade via multiple intermediates to a variety of stable end products; T1/2 ranging from weeks to decades.
- Telomer alcohols can be degraded to shorter odd and even chain products by unzipping during a variety of processes.
- Chain length affects environmental transport with shorter chain chemicals being generally more mobile than longer ones with the similar structure.
- For chemicals that degrade incorporating known pathways such as telomer alcohols, sulfonamides, and phosphates, analogy to existing chemical data provides indication of products, intermediates and rates.

PFASs Assessment "Rules of Thumb"

EXPOSURE

- Releases to the environment from consumer products, AFFF, treated articles, etc. are of at least equal concern as industrial releases.

HAZARD

- Intermediates in the degradation to stable products may be much more toxic than parent or end product.

- Understanding of toxicokinetics (e.g., plasma concentrations and half-lives across species and chemicals needs to be considered in risk assessment.

- With notable exceptions, short and long chain compounds are less toxic than intermediate chain for a given structure.

Ongoing Assessments Advances

- Continuously Re-visit “Rules of Thumb”
- Develop New Chemicals Categories to:
  - Streamline analog identification/read-across
  - Develop strategic, tiered testing approaches
- Identify critical Data Gaps

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To learn more about EPA's Perflouro Activities:

- http://www.epa.gov/oppt/pfoa/

To learn more about EPA's New Chemicals Program:

- http://www.epa.gov/oppt/newchems/